Docket No.: 480062004300
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
M. David BUTTS et al.

Application No.: 10/803,279 Confirmation No.: 5654

Filed: March 18, 2004 Art Unit: 3763

For: CATHETER CONNECTOR Examiner: L. A. Bouchelle

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

This is in response to the non-final Office Action dated September 20, 2007, for which a response was due on December 20, 2007. Filed herewith is a Petition and fee for a 2 month extension of time, thereby extending the deadline for response to February 20, 2007. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the remarks presented herein are respectfully requested.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 10 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please amend paragraph [0010] of the specification as follows:

[0010] With particular reference to a catheter that has [[a]] been subcutaneously placed, in which an extracorporeal portion is to be connected to a coupling hub, systems such as that shown in FIG. 1 have been traditionally utilized. As shown, a catheter 20 is attached to a coupling hub 12 through three pre-assembled pieces. The proximal end of the catheter 20 is slid through strain relief sleeve 18, distal coupling 16 and compression sleeve 14. The proximal end of the catheter 20 is then slid over the cannula of coupling hub 12. Distal coupling 16 is snapped into coupling hub 12, exerting pressure against compression sleeve 14, which in turn retains catheter 20 on the cannula coupling hub 12. While such a connection system may be adequate for providing a secure connection, assembly can prove problematic due to the small size of the pieces involved as well as the extremely limited space with which the physician typically has to work. Moreover, the manufacture of several different pieces may lengthen the time to manufacture, as well as the cost associated therewith.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A catheter connector comprising:

a body comprising a cannula and a tail, said cannula extending from a distal end of said body and including a blunt distal end configured for insertion into ~~to receive~~ a proximal end of a catheter following placement of a distal end of the catheter in a patient ~~thereon~~, said tail extending from a proximal end of said body configured for insertion into ~~to receive~~ a distal end of a tube ~~thereon~~, wherein said body establishes ~~is configured for~~ fluid communication between the tube and the catheter ~~flow therethrough~~; and

a securement device attached to ~~said~~ the distal end of the body ~~at said distal end~~, comprising mating portions configured to secure said catheter to said body by locking together directly around said catheter following insertion of the cannula into the catheter ~~positioning of said catheter over said cannula~~.

2. (Original) The catheter connector according to claim 1, wherein said body and said securement device are unitary.

3. (Original) The catheter connector according to claim 2, wherein said securement device is attached to said body by a living hinge.

4. (Withdrawn) The catheter connector according to claim 1, wherein said securement device is separately attachable to said body.

5. (Original) The catheter connector according to claim 1, wherein said body further comprises a ribbed region.

6. (Original) The catheter connector according to claim 1, wherein said cannula is comprised of metal.

7. (Original) The catheter connector according to claim 1, wherein said tail comprises a barbed end.

8. (Currently amended) The catheter connector according to claim 1, wherein ~~an open~~ the blunt distal end of said cannula comprises a rounded edge.

9. (Original) The catheter connector according to claim 1, wherein an open end of said cannula comprises a beveled edge.

10. (Original) The catheter connector according to claim 1, wherein said mating portions are connected by a living hinge.

11. (Original) The catheter connector according to claim 1, wherein said mating portions comprise catheter receiving portions having distal ends that are funneled outward.

12. (Original) The catheter connector according to claim 1, wherein said mating portions comprise catheter receiving portions that together accommodate said catheter when closed therearound so that a tight seal is formed between said catheter receiving portions and said catheter.

13. (Original) The catheter connector according to claim 1, wherein said mating portions comprise locking portions having rounded distal ends.

14. (Original) The catheter connector according to claim 1, further comprising a winged covering apparatus positioned over at least a portion of said body.

15. (Original) The catheter connector according to claim 14, wherein said winged covering apparatus is made of silicone.

16. (Original) The catheter connector according to claim 14, wherein said body further comprises a region having a non-uniform outer surface, said winged covering apparatus comprising an inner surface configured to mesh with said non-uniform outer surface to prevent relative movement of said body with respect to said winged covering apparatus.

17. (Original) The catheter connector according to claim 1, wherein said body further comprises a head positioned at a distal end thereof, said cannula extending from said head.

18. (Original) The catheter connector according to claim 17, wherein said mating portions are separately attached to said body and comprise cut-away portions to receive said head therein.

19. (Original) The catheter connector according to claim 18, wherein said head is slightly smaller than said cut-away portions.

20. (Original) The catheter connector according to claim 1, wherein said mating portions further comprise catheter gripping liners.

21. (Previously presented) An assembly for connecting a catheter to extracorporeal medical equipment, comprising:

a catheter connector comprising a body having a lumen therethrough and a securement device attached at two separate locations to said body at a distal end thereof, said securement device configured to secure a catheter to said body such that said body lumen is in fluid communication with said catheter;

a tube connected at one end to a proximal end of said body and at an opposite end to a hub such that said body lumen is in fluid communication with said hub; and

a covering positioned over at least a portion of said body and said tube, said covering being adapted for attachment to a patient.

22. (Previously presented) The catheter connector according to claim 21, wherein said body includes a catheter receiving member extending from a distal end thereof.

23. (Previously presented) The catheter connector according to claim 22, wherein the catheter receiving member includes a first and second cannula configured to receive a dual lumen catheter thereover.

24. (Original) The catheter connector according to claim 21, wherein said covering comprises winged portions.

25. (Original) The catheter connector according to claim 21, further comprising a sleeve to secure said tube to said hub.

26. (Withdrawn) A catheter connector comprising:

a stem having at least one lumen extending longitudinally from a proximal end to a distal end, said stem comprising at least one prong at said distal end, configured for insertion into a lumen of a catheter;

at least one extension tube in fluid communication with said lumen of said stem;

a hub surrounding at least a portion of said stem, configured for attachment to a patient;

a clamp coupled to said stem, configured to close around a tip of said prong following insertion of said prong into said lumen of said catheter; and

a collar movable from a first position to a second position, wherein said collar in said second position retains said clamp in a closed position.

27. (Withdrawn) The catheter connector according to claim 26, wherein said stem comprises a first and second prong, having a gap therebetween.

28. (Withdrawn) The catheter connector according to claim 27, wherein said stem comprises a first and second lumen in respective fluid communication with said first and second prong.

29. (Withdrawn) The catheter connector according to claim 28, further comprising a first and second extension tube in respective fluid communication with said first and second lumen.

30. (Withdrawn) The catheter connector according to claim 26, wherein said tip of said prong is larger than said lumen of said catheter.

31. (Withdrawn) The catheter connector according to claim 26, wherein said stem further comprises a stop positioned proximal of said prong, said stop having a diameter greater than the diameter of an outer wall of said catheter.

32. (Withdrawn) The catheter connector according to claim 26, wherein said clamp comprises a base and a pair of matching members, wherein each of said matching members are attached to said base via a living hinge.

33. (Withdrawn) The catheter connector according to claim 26, wherein said clamp and said collar are configured for locking engagement with one another.

34. (Withdrawn) The catheter connector according to claim 33, wherein said clamp comprises a raised section around an outer wall thereof and said collar comprises a recessed section on an inner wall thereof, wherein movement of said recessed section over said raised section creates said locking engagement.

35. (Withdrawn) The catheter connector according to claim 33, wherein said clamp and said collar are configured with mating thread portions for screwing one to the other.

36. (Withdrawn) An attachable bifurcation comprising:

a stem enclosing a first and second lumen and comprising a first and second prong at a distal end thereof, wherein said first and second prongs are configured for insertion into the proximal end of a dual lumen catheter;

a first and second extension tube in respective fluid communication with said first and second lumens of said stem;

a hub surrounding at least a portion of said stem, configured for attachment to a patient;

a clamp coupled to said stem, configured to close around said first and second prongs following insertion of said prongs into said dual lumen catheter; and

a collar movable from a first position to a second position, wherein said collar in said second position retains said clamp in a closed position.

37. (Withdrawn) The attachable bifurcation according to claim 35, wherein each of said first and second prongs have a tip that is larger than said lumen of said catheter.

38. (Withdrawn) The attachable bifurcation according to claim 35, wherein said stem further comprises a stop positioned proximal of said prongs, said stop having a diameter greater than the diameter of an outer wall of said catheter.

39. (Withdrawn) The attachable bifurcation according to claim 35, wherein said clamp comprises a base and a pair of matching members, wherein each of said matching members are attached to said base via a living hinge.

40. (Withdrawn) The attachable bifurcation according to claim 35, wherein said clamp and said collar are configured for locking engagement with one another.

41. (Withdrawn) The attachable bifurcation according to claim 39, wherein said clamp comprises a raised section around an outer wall thereof and said collar comprises a recessed section on an inner wall thereof, wherein movement of said recessed section over said raised section creates said locking engagement.

42. (Withdrawn) A catheter connector for attachment to a catheter, wherein said catheter comprises at least one lumen and a hub attached to a proximal end thereof, comprising:

at least one cannula; and

a latching mechanism disposed near a proximal end of said cannula, said latching mechanism extending outwardly from a longitudinal axis of said cannula in a first position and being movable inward toward said longitudinal axis in a second position, said latching mechanism being biased in said first position.

43. (Withdrawn) The catheter connector according to claim 41, wherein said hub comprises at least one lumen in fluid communication with said at least one catheter lumen and internal indents shaped to receive said latching mechanism.

44. (Withdrawn) The catheter connector according to claim 41, wherein said catheter connector comprises two cannulas and said catheter comprises two lumens.

45. (Withdrawn) The catheter connector according to claim 41, wherein said cannula has the same shape in cross-section as that of said lumen.

REMARKS

The Office Action mailed September 20, 2007 (hereinafter, "Office Action"), has been reviewed and the Examiner's comments considered. At the outset, Applicants appreciate the Examiner's withdrawal of the previous claim rejections in view of the arguments submitted August 31, 2007. Claims 1-45 are pending in this application. Claims 4 and 26-45 are withdrawn from consideration. Claims 1 and 8 are amended herein. The specification is amended herein to correct a typographical error. Applicants submit that no new matter or issues have been introduced.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 6, 9, 10-13, and 17-20 stand rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 4,596,571 to Bellotti et al. (hereinafter, "Bellotti I") in view of European Patent Application Publication No. 0183396 to Bellotti et al. (hereinafter, "Bellotti II"). Claims 2, 3 and 7 stand rejected under Section 103(a) as being unpatentable over Bellotti I in view of Bellotti II in view of U.S. Patent No. 4,723,948 to Clark et al. (hereinafter, "Clark"). Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bellotti I in view of Bellotti II in view of U.S. Patent No. 5,454,409 to McAffer (hereinafter, "McAffer"). Claims 14-16 and 21-25 stand rejected under Section 103(a) as being unpatentable over Bellotti I in view of Bellotti II, also in view of International Patent Publication No. WO 02/058776 to Wilson et al. (hereinafter, "Wilson"), and in further view of U.S. Patent Application Publication No. 2003/0065288 to Brimhall et al. (hereinafter, "Brimhall"). Applicants respectfully traverse these rejections.

Independent claim 1 is amended herein to recite, *inter alia*, "said cannula extending from a distal end of said body and including a *blunt distal end* configured for insertion into a proximal end of a catheter *following placement of a distal end of the catheter in a patient*...and a securement device attached to the distal end of the body, comprising mating portions configured to secure said catheter to said body *by locking together directly around said catheter* following insertion of the cannula into the catheter" (emphasis added). Support for the amendments to claim 1 can be found in the originally filed application at, for example, paragraphs [0012], [0044], [0048] and FIGS. 8-9.

The Office Action alleges that the combination of Bellotti I and Bellotti II render independent claim 1 unpatentable because Bellotti II shows the missing feature of a body having a tail configured to receive a tube thereon. As discussed in the response filed August 31, 2007, Bellotti I is directed to a system to connect an administration set to a solution container for peritoneal dialysis. Bellotti II is directed to the same type of system (*see, e.g.*, p. 4, lines 10-15 and p. 4, line 26 to p. 5, line 21). Both Bellotti I and Bellotti II show and describe a flange connector including a pair of hollow shell halves that pivot about hinge means to a closed position forming a tubular member. The flange connector is designed to be inserted over flanges on the administration set and solution container, respectively.

Independent claim 1, on the other hand, recites features not shown or described by the combination of Bellotti I and II, including at least: 1) a cannula with a *blunt distal end*, 2) configured for insertion into a proximal end of a catheter *following placement of a distal end of the catheter in a patient*, and 3) a securement device including mating portions configured to secure said catheter to said body *by locking together directly around said catheter*. Accordingly, a *prima facie* case of obviousness is not established through the combination of Bellotti I and II because not all of the claim elements are shown or described by the cited combination.

First, Applicants note that dependent claim 8, reciting that the distal end of the cannula comprises a rounded edge, was rejected as obvious over the Bellotti I and II combination in view of McAffer. However, McAffer does not show or describe a cannula with a *blunt distal end* that is configured for insertion into a proximal end of a *catheter* following placement of a distal end of the catheter in a patient, and therefore, does not provide the features missing from the combination of Bellotti I and II. At most, McAffer shows a cannula with a rounded *tip* configured for penetration of a *septum*. Moreover, Applicants submit that the alleged cannula of Bellotti I, identified as spike member 12, is not configured for insertion into a proximal end of a catheter as claimed, but like McAffer is designed for piercing a membrane (*see, e.g.*, col. 2, ll. 65-66). Further, different from locking together *directly* around a catheter, the hollow shell halves of Bellotti I and II have grooves designed for interfacing with flanges associated with the administration set (*i.e.*, flanges 44 and 56 of Bellotti I (col. 3, ll. 42-61); flanges 36 and 62 of Bellotti II (p. 6, line 21 to p. 7, l. 9).

Therefore, Applicants respectfully submit that the asserted combination does not show or describe all of the claim elements of independent claim 1. Thus, independent claim 1, and claims 6, 8, 9, 10-13, and 17-20 depending therefrom, are patentable over the cited combinations of Bellotti I and II, and Bellotti I and II in view of McAffer. Accordingly, Applicants request favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

Regarding dependent claims 2, 3 and 7, without conceding the propriety of the asserted combination, in view of the above, Applicants submit that each rejected claim depends from patentable independent claim 1 and is therefore patentable. Accordingly, Applicants respectfully request favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

Regarding dependent claims 14-16, without conceding the propriety of the asserted combination, in view of the above, Applicants submit that each rejected claim depends from patentable independent claim 1 and is therefore patentable. Accordingly, Applicants respectfully request favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

Independent claim 21 recites, *inter alia*, "a securement device attached at two separate locations to said body at a distal end thereof."

In the response filed August 31, 2007, Applicants noted for the *third time* that the asserted combination of Bellotti and Wilson fail to show or describe the claimed feature of a securement device attached at *two separate locations to said body at a distal end thereof.* The Office Action again fails to provide any support for this feature in the asserted combination of Bellotti I, Bellotti II, Wilson and Brimhall. Because the securement device and its attachment to the catheter connector body are positive limitations set forth in claim 21, failure of the Office Action to point out purportedly anticipating or obviating structure for the aforementioned claimed feature prevents Applicants from fully responding to the rejection in seeking allowance of the pending claims. Applicants therefore repeat herein the request set forth in the response filed August 31, 2007, that in the event that the rejection is maintained the Office identify with specificity the structure in the cited art to support a *prima facie* case of obviousness.

In addition to the contention that the asserted combination does not show or describe all of the claim elements, Applicants asserted that a *prima facie* case of obviousness is not established through the combination of Bellotti I and Wilson because there is a clear lack of suggested desirability to combine. Said another way, the combination of features from Bellotti I and Wilson is not a predictable use of prior art elements according to their established functions. This lack of predictable use is unchanged with the addition of essentially the same subject matter of Bellotti II. As set forth on p. 4 of the response filed August 31, 2007, in reply to the Office's justification of the suggested desirability to combine:

> The shroud 18 is the feature of Bellotti that is intended to "surround and protect the connection site between fluid conduits." As such, there is no suggested desirability to add another element (i.e., the cover of Wilson) to complicate the device for a redundant purpose. Further, the disclosure of "diverse environments" does not lead to the notion of a completely different device (i.e., a device "adapted for attachment to a patient" as recited in instant claim 21 rather than a device designed to "surround and protect the connection site" as described by Bellotti). Finally, the disclosure of "parenteral fluids" is not germane to the device but to the fluid within the solution container. As set forth in the Response, adding a covering adapted for attachment to a patient to the proximal end of an administration set intended to be suspended in air is not a desirable combination at least because the covering would serve no purpose.

This contention was not addressed in the Office Action, presumably due to the new grounds for rejection. However, because the new grounds consisted only of the addition of Bellotti II, which is directed to essentially the same subject matter of Bellotti I, Applicants assertion of lack of predictable use of elements is believed to be relevant to the standing rejection of independent claim 21. Thus, if the rejection is maintained, Applicants respectfully request that the Office address this argument in the interest of compact prosecution.

In view of the above, Applicants submit that a *prima facie* case of obviousness is not established by the asserted combination at least because: 1) not all of the claim elements are shown

or described, and 2) there is a lack of predictable use of elements according to their established function. Thus, independent claim 21, and claims 21-25 depending therefrom, are patentable over the cited combination of Bellotti I, Bellotti II, Wilson and Brimhall. Accordingly, Applicants request favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 480062004300. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: February 20, 2008

Respectfully submitted,

Electronic signature: /Todd W. Wight/
Todd W. Wight
Registration No.: 45,218
MORRISON & FOERSTER LLP
19900 MacArthur Boulevard
Irvine, California 92612-2445
(949) 251-7189